Exhibit B

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

AZURITY PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	Case No. 8:21-cv-2515-TPB-SPF
CORERX, INC.,	)	
Defendant,	)	
v.	)	
BIONPHARMA INC.,	)	
Intervenor-Defendant (Motion Pending)	)	

THIRD-PARTY BIONPHARMA INC.'S MOTION TO INTERVENE AND MEMORANDUM OF LAW IN SUPPORT

Third-party Bionpharma Inc. ("Bionpharma") respectfully moves this Court pursuant to Fed. R. Civ. P. 24(a)(2) and 24(b)(1)(B) for leave to intervene as a defendant. Bionpharma does not seek to reopen this case; Bionpharma only seeks to intervene to oppose the Joint Motion to Reopen Case for Limited Purpose of Correcting Dismissal (D.I. 18, "Joint Motion"), which seeks to deprive Bionpharma of a claim preclusion defense it has in parallel, related litigation involving the same accused product and asserted patents that are at issue here.

Broadly speaking, Bionpharma seeks leave to intervene in this action to

defend and exonerate its 1 mg/mL enalapril maleate oral solution prescription drug product ("Bionpharma's ANDA product"), and to dispell the cloud of litigation that threatens its manufacturing and supplier relationships, such as that with Defendant CoreRx, Inc. ("CoreRx").

More particularly, Bionpharma has a compelling interest in opposing the Joint Motion (D.I. 18), as the resolution of that Motion will impact a pending motion to dismiss that Bionpharma has filed in connection with related litigation between Azurity and Bionpharma currently pending in the District of Delaware. Bionpharma is attempting to prevent an end-run around prior decisions adverse to Plaintiff with respect to the patents-in-suit. Granting this motion will not prejudice the rights of any existing party, and it appears that no party wishes for this case to be reopened (*id.*). Denying the motion, however, will greatly prejudice the interests of Bionpharma.

Before the case was dismissed, Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity") indicated that it opposes a motion by Bionpharma to intervene in the case, while CoreRx did not consent but did not state that it would oppose this Motion.

INTRODUCTION AND FACTUAL BACKGROUND

Bionpharma is a generic drug company that develops and commercially markets affordable quality generic medications. In 2018, Bionpharma prepared and filed with the U.S. Food and Drug Administration ("FDA") Abbreviated New Drug

Application ("ANDA") No. 212408 ("Bionpharma's ANDA"), which sought FDA approval to market a 1 mg/ml enalapril maleate oral solution as generic to Azurity's Epaned® antihypertensive prescription drug product ("Bionpharma's ANDA product"). Bionpharma's ANDA was approved on August 10, 2021, and Bionpharma commercially launched its ANDA product shortly thereafter.

In response to the filing of Bionpharma's ANDA, Azurity began instituting what would become three waves of lawsuits against Bionpharma in the United States District Court for the District of Delaware before the Honorable Leonard P. Stark, alleging that Biopharma's ANDA and ANDA product infringe Azurity's Epaned® patent estate ("the Delaware Suits"). The First[1] and Second[2] Wave Suits were resolved in Bionpharma's favor,[3] and the Third Wave Suits,[4] which assert the same patents asserted here against CoreRx,[5] remain pending after Bionpharma recently defeated a preliminary injunction motion from Azurity seeking to remove

[1] *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-LPS and 19-1067-LPS (D. Del.). Azurity is successor-in-interest to Silvergate Pharmaceuticals, Inc., the named plaintiff in the First and Second Wave Suits.

[2] *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 20-1256-LPS (D. Del.).

[3] *See Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 18-1962-LPS, 2021 WL 1751148 (D. Del. Apr. 29, 2021); *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 20-1256-LPS (D. Del.), D.I. 106, Joint Stipulation of Dismissal.

[4] *Azurity Pharm., Inc. v. Bionpharma Inc.*, C.A. Nos. 21-1286-LPS, 21-1455 LPS (D. Del.).

[5] U.S. Patent Nos. 11,040,023 ("'023 patent") and 11,141,405 ("'405 patent") (collectively, "the patents-in-suit").

Bionpharma's ANDA product from the market.[6]

Over three years after Azurity began instituting the Delaware Suits, in what appears to be an attempt to circumvent Judge Stark's rulings, Azurity brings this action against CoreRx, the company that Bionpharma contracted with to (in collaboration with Bionpharma) develop Bionpharma's ANDA product, and to commercially manufacture and supply Bionpharma's ANDA product, alleging that, *inter alia*, CoreRx's commercial manufacture and supply of Bionpharma's ANDA product infringes the patents-in-suit. D.I. 1, Compl. ¶ 1. Azurity also filed an essentially duplicative action against CoreRx in the District of Delaware. *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS (D. Del.) ("Delaware CoreRx suit"), D.I. 1, Compl.

Bionpharma clearly has an interest in the subject matter of this litigation—the continued, uninterrupted manufacture and supply of its ANDA product. However, Azurity is owned by NovaQuest Capital Management ("NovaQuest"), a private equity firm,[7] and earlier this year NovaQuest acquired CoreRx.[8] Because of the

[6] *See Azurity Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.), D.I. 87, Oral Order.

[7] Ex. B, M&A Deal Summary, *NovaQuest Capital Management Acquires Azurity Pharmaceutical*, MERGR.COM, https://mergr.com/novaquest-capital-management-acquires-azurity-pharmaceuticals (last visited Nov. 12, 2021).

[8] Ex. C, *NovaQuest Private Equity Acquires CoreRx, Inc.*, BUSINESS WIRE (Jan. 19, 2021), https://www.businesswire.com/news/home/20210119005200/en/NovaQuest-Private-Equity-Acquires-CoreRx-Inc.

common ownership between Azurity, Bionpharma's competitor, and CoreRx, Bionpharma's commercial manufacturer and supplier,[9] Bionpharma has reason to believe that its interest in the subject of this action may not be adequately represented.[10] Thus, Bionpharma respectfully seeks leave to intervene as a matter of right pursuant to Fed. R. Civ. P. 24(a)(2). Alternatively, the patents-in-suit are also being asserted against Bionpharma in the Third Wave Suits, and Bionpharma has raised non-infringement and invalidity defenses that share with the instant action common questions of law and fact. Thus, permissive intervention under Fed. R. Civ. P. 24(b)(1)(B) is warranted.

Finally, on November 26, 2021, Azurity voluntarily dismissed the instant action and the Delaware CoreRx suit. D.I. 16, Notice of Dismissal; Delaware CoreRx suit, D.I. 6, Notice of Dismissal. By operation of law, the second of those two voluntary dismissals was a adjudication upon the merits and, thus, a with

[9] Upon information and belief, NovaQuest owns and controls Azurity and CoreRx through an intermediate holding company, CutisPharma,. Ex. D, *NovaQuest Capital Management Acquires CutisPharma, Inc.*, PR NEWSWIRE (Mar. 26, 2018), https://www.prnewswire.com/news-releases/novaquest-capital-management-acquires-cutispharma-inc-300619121.html. Azurity identifies CutisPharma Intermediate Holdings Inc. as owning 10% or more of its stock. D.I. 3, Pl.'s L.R. 3.03 Disclosure Statement.

[10] Because the plaintiff patent owner (Azurity) and defendant accused infringer (CoreRx) are actually commonly-owned affiliates, there is no justiciable case or controversy between adverse litigants sufficient to support subject matter jurisdiction over Azurity's patent infringement claims against CoreRx. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). As such, Bionpharma has raised a subject matter jurisdiction defense in its proposed answer (Ex. A) and, if permitted to intervene, will explain to the Court that Azurity's Joint Motion (D.I. 18) should be denied because, *inter alia*, the instant lawsuit and a duplicative suit Azurity filed against CoreRx in Delaware represent sham litigation that was about enforcing legitimate patent rights.

prejudice dismissal of Azurity's infringement claims against CoreRx and, in particular, Bionpharma's ANDA product. FED. R. CIV. P. 41(a)(1)(B). Because Bionpharma and CoreRx are in privity with respect to Bionpharma's ANDA product and Azurity's '023 and '405 patent infringement claims, Bionpharma has moved to dismiss the Third Wave Suits on claim preclusion grounds and the "two dismissal rule" of Rule 41(a)(1)(B).[11] In response, Azurity has filed in the instant action Joint Motion to vacate its own notice of dismissal. D.I. 18. Because the granting of the Joint Motion could potentially deprive Bionpharma of its non-infringement defense based on the "two dismissal rule" and claim preclusion, and undermine Bionpharma's pending Motion to Dismiss the Third Wave Suits, Bionpharma has a compelling interest in opposing the Joint Motion which is not adequately represented by the existing parties in this action.

For the foregoing reasons, explained more fully below, Bionpharma respectfully requests that it be granted leave to intervene as a defendant in this action, and attaches hereto as Exhibit A its proposed Answer in Intervention.[12]

ARGUMENT

I. LEGAL STANDARD

To intervene by right, a movant must show: (1) its application to intervene is

[11] *Azurity Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.), D.I. 97; *Azurity Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 21-1455 LPS (D. Del.), D.I. 12.

[12] Exhibit A (Bionpharma's Answer in Intervention) is submitted herewith as required by Fed. R. Civ. P. 24. Bionpharma does not, however, seek to reopen this case.

timely; (2) it has an interest relating to the property or transaction which is the subject of the action; (3) it is so situated that disposition of the action, as a practical matter, may impede or impair its ability to protect that interest; and (4) its interest is represented inadequately by the existing parties to the suit. Fed. R. Civ. P. 24(a)(2); *Tech. Training Assocs., Inc. v. Buccaneers Ltd. P'ship*, 874 F.3d 692, 695-96 (11th Cir. 2017). For permissive intervention, a movant must show: (1) its motion is timely; (2) it has a claim or defense that shares a common question of law or fact with the main action; and (3) its intervention will not cause undue delay or prejudice the rights of the original parties. FED. R. CIV. P. 24(b)(1)(B); *Chiles v. Thornburgh*, 865 F.2d 1197, 1213 (11th Cir. 1989).

II. BIONPHARMA SHOULD BE GRANTED INTERVENTION AS A MATTER OF RIGHT

Fed. R. Civ. P. 24(a)(2) provides the Court, on timely motion, "must permit" "anyone to intervene who … claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Bionpharma meets all of these requirements and is entitled to intervene as a matter of right.

A. Bionpharma's Motion is Timely

In determining whether a motion to intervene is timely, courts consider: (1) the length of time during which the proposed intervenor knew or reasonably should

have known of its interest in the case before moving to intervene; (2) the extent of prejudice to the existing parties as a result of the proposed intervenor's failure to move for intervention as soon as it knew or should have known about its interest; (3) the extent of prejudice to the proposed intervenor if the motion is denied; and (4) the existence of unusual circumstances militating either for or against a determination that the motion to intervene was timely. *Ga. v. U.S. Army Corp. of Eng'rs*, 302 F.3d 1242, 1259 (11th Cir. 2002) (citation omitted).

Bionpharma files this Motion mere hours after Azurity's and CoreRx's attempt to modify Azurity's own voluntary notice of dismissal (D.I. 18). Bionpharma's motion therefore does not prejudice the other parties. Bionpharma moved for intervention as soon as it knew or should have known about its interest and Azurity's attempt to modify its own notice of dismissal. *See Fla. Med. Ass'n v. Dept. of Health, Educations & Welfare*, No. 3:78-cv-178-J-34MCR, 2011 WL 4459387, at *5-6, *8-9, *16 (M.D. Fla. Sept. 26, 2011).

Regarding the third factor, Bionpharma should be allowed to intervene to defend the manufacture and commercialization of its ANDA product, or it will suffer substantial prejudice. Plaintiff has alleged that Bionpharma's product infringes in other venues, so Bionpharma would suffer great prejudice if it is not allowed to oppose what will amount to a procedural end-run around adverse rulings elsewhere. No unusual circumstances exist for finding Bionpharma's motion is not timely.

Thus, Bionpharma respectfully submits that the Motion is timely.

B. Bionpharma Has an Enormous Interest in the Subject Matter of this Litigation

As to the second element, a non-party has a sufficient interest in the property or transaction at issue when the nonparty has a "direct, substantial, legally protectable interest in the proceedings." *Chiles*, 865 F.2d at 1213.

As explained above, Bionpharma contracted with CoreRx to, in collaboration with Bionpharma, develop Bionpharma's ANDA product, and CoreRx currently commercially manufactures and supplies Bionpharma's ANDA product. Bionpharma has been commercially marketing its ANDA product in the United States since August 17, 2021, and is currently enjoying a 180-day period of non-patent marketing exclusivity granted to Bionpharma by FDA because Bionpharma was the first generic drug company to develop and seek approval for a generic version of Epaned® prior to the expiration of Azurity's Epaned® patents. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Bionpharma also recently defeated a preliminary injunction motion from Azurity seeking to remove Bionpharma's ANDA product from the market based on one of the two patents-in-suit (the '023 patent). *See Azurity Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.), D.I. 87, Oral Order.

In its Complaint, Azurity alleges that "CoreRx's manufacture, use, sale, importation, and/or offer to sell and/or inducement of or contributing to others to do

the foregoing within the United States of [Bionpharma's ANDA product] prior to the expiration of the patents-in-suit" constitutes infringement of the patents-in-suit, and seeks, *inter alia*, to enjoin CoreRx from manufacturing and supplying Bionpharma's ANDA product. D.I. 1, Compl. ¶¶ 1, 33-57; *id*. at Prayer for Relief. Thus, Bionpharma has an enormous interest in the subject matter of this litigation, and Azurity recognizes this: in its Local Rule 3.03 Disclosure Statement (D.I. 3), Azurity represents that Bionpharma is an "entity which is likely to be an active participant in the proceedings." D.I. 3, Pl.'s L.R. 3.03 Disclosure Statement at 2. Moreover, Bionpharma and Azurity have been litigating Bionpharma's ANDA product and Azurity's Epaned® patents for the last three years in the District of Delaware, and are currently litigating the alleged infringement of the patents-in-suit by Bionpharma's ANDA product in that court. The nearly complete overlap in the subject matter of the instant suit and the Third Wave Suits—which also involve the patents-in-suit and Bionpharma's ANDA product—is further evidence of the enormous interest Bionpharma has in the subject of this litigation.

Finally, as explained above, because Azurity has voluntarily dismissed the instant action and the duplicative Delaware CoreRx suit, Bionpharma has a claim preclusion defense that is currently the subject of a motion to dismiss that Bionpharma has filed in the Third Wave Suits in Delaware based on the "two dismissal rule" of Fed. R. Civ. P. 41(a)(1)(B). Azurity seeks to deprive Bionpharma

of this defense by jointly moving to re-open this case for the limited purpose of substituting its notice of dismissal with a joint stipulation of dismissal without prejudice. Bionpharma should be allowed the opportunity to explain to this Court why the Joint Motion should be denied, including because Azurity has misused the Federal courts by filing sham litigation against a commonly-owned affiliate, CoreRx.

For at least the foregoing reasons, Bionpharma has a sufficient interest in this litigation justifying intervention as of right.

C. Disposal of this Action Without Bionpharma's Participation Would Prejudice Bionpharma's Ability to Protect Its Interest

Unless Bionpharma is allowed to intervene in this action, its interests would not be adequately protected. *Chiles*, 865 F.2d at 1214. Progression of the case without Bionpharma's involvement would risk inconsistent rulings and judgments with the Third Wave Suits currently pending in the District of Delaware. Bionpharma has been involved in litigation with Azurity over Bionpharma's ANDA product and Azurity's Epaned® patents for the last three years in the District of Delaware, and is currently litigating the patents-in-suit there and whether Bionpharma's ANDA product infringes those patents. *See* the Third Wave Suits; *see also Honeywell Int'l Inc. v. Audiovox Commc'ns Corp.*, C.A. No. 04-1337-KAJ, 2005 WL 2465898 at *1, 4 (D. Del. May 18, 2005) (granting motion to intervene "because it puts a willing manufacturer defendant in the forefront of litigation aimed

squarely at its product."). Disposal of this suit without Bionpharma's involvement may impede Bionpharma's ability to ensure that its ANDA product is found to not infringe any valid claim of the patents-in-suit, and to ensure that Bionpharma is able to continue marketing its ANDA product and providing consumers with a lower-priced generic alternative to Epaned®.

D. Bionpharma's Interest Is Represented Inadequately by the Existing Parties

The fourth factor, that the interest is represented inadequately by the existing parties to the suit, requires a "minimal" showing "that representation of [one's] interest 'may be' inadequate." *Chiles*, 865 F.2d at 1214 (citing *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972) (granting intervention as of right)). Bionpharma needs to show only the possibility that its interests may be different than CoreRx. *Id*. at 1214-15. As explained above, NovaQuest, which owns Azurity, recently acquired CoreRx. Thus, because of the common ownership between Azurity, the Plaintiff patent owner in this suit, and CoreRx, the accused infringer, Bionpharma has a reasonable basis to believe that its interest in the subject matter of this litigation may be different, and therefore, inadequately represented by the current parties.[13] Further, Bionpharma is "uniquely situated to understand and defend its own product," *Honeywell*, 2005 WL 2465898, at *4, and therefore meets

[13] Indeed, as Bionpharma will explain if allowed to intervene, there is likely no justiciable case or controversy between adverse litigants sufficient to support this Court's exercise of subject matter jurisdiction over Azurity's patent infringement claims against CoreRx.

the "minimal" standard for showing inadequate representation. Bionpharma thus respectfully submits that it should be granted intervention as a matter of right under Fed. R. Civ. P. 24(a).

III. ALTERNATIVELY, BIONPHARMA SHOULD BE GRANTED PERMISSIVE INTERVATION

Bionpharma's motion is timely and satisfies each of the factors required for intervention as of right. But even if the Court concluded otherwise, it may nevertheless permit intervention on a motion to intervene if it finds that Bionpharma "has a claim or defense that shares with the main action a common question of law or fact." FED. R. CIV. P. 24(b)(1)(B). Here, Bionpharma has claims and defenses that have questions of law and fact in common with this action, such as non-infringement and invalidity in response to Plaintiff's infringement contentions with respect to the patents-in-suit.

A proposed permissive intervenor must show: (1) its motion to intervene is timely; and (2) its defense and the main action share a common question of law or fact. *Chiles*, 865 F.2d at 1213.

A. Bionpharma's Motion is Timely

As explained above in connection with Bionpharma's arguments to support intervention as a matter of right, this Motion is timely.

B. This Action is Duplicative of the Delaware Suits

Bionpharma has claims and defenses to the patents-in-suit that share common

questions of law and fact with this action: namely, the invalidity of the patents-in-suit, and the non-infringement of Bionpharma's ANDA product. In fact, Bionpharma and Azurity are already litigating those claims and defenses in connection with the currently pending Third Wave Suits in Delaware. Bionpharma's invalidity and non-infringement defenses are presumably be the same defenses that CoreRx will be expected to raise here. Thus, it cannot be disputed that Bionpharma has claims and defenses that share common questions of law and fact with this suit.

C. Intervention Will Not Cause Delay or Prejudice the Rights of Azurity or CoreRx

Finally, Bionpharma brings this Motion before CoreRx has even responded to the Complaint. (D.I. 16.) Bionpharma does not seek to reopen this case; only to oppose the Joint Motion (D.I. 18), which seeks to deprive Bionpharma of a claim preclusion defense that Bionpharma has to the patents-in-suit involving the same accused product in the instant suit. However, should this case be reopened and go forward, Bionpharma's defenses will likely overlap completely with CoreRx's defenses. Thus, intervention will impose no delay in resolving this action (and may in fact speed it up given Bionpharma's familiarity with, and history litigating, Azurity's Epaned® patent family).

Furthermore, intervention by Bionpharma would not prejudice the rights of Azurity or CoreRx in any way. Bionpharma and Azurity are already competitors actively litigating the same patents and accused activity in this action in connection

with the Third Wave Suits currently pending in the District of Delaware. Meanwhile, CoreRx and Bionpharma are in privity with one another as to the development and commercialization of Bionpharma's ANDA product, and thus likely have the same defenses to Azurity's infringement claims. As such, Bionpharma respectfully requests that it be granted permission to intervene.

CONCLUSION

Bionpharma respectfully requests that it be allowed to intervene as a matter of right pursuant to Fed. R. Civ. P. 24(a)(2). Alternatively, Bionpharma submits that it meets the requirements for permissive intervention under Fed. R. Civ. P. 24(b)(1)(B), and respectfully requests that it be granted leave to intervene permissively.

LOCAL RULE 3.01(g) CERTIFICATION

Bionpharma hereby certifies that on November 15, 2021, before this case was dismissed, Bionpharma and Azurity conducted a telephonic meet and confer concerning Bionpharma's proposed motion to intervene, and Azurity opposes it.

Bionpharma further certifies that it raised intervention a with CoreRx during a telephone conference held on November 11, 2021. Bionpharma and CoreRx further met and conferred over email, where CoreRx ultimately informed Bionpharma that it would not consent to the Motion; however, CoreRx did not

indicate that it would oppose the Motion.

Dated: December 10, 2021

Respectfully submitted,

CARLTON FIELDS, P.A.

By: /s/ Eleanor M. Yost
Eleanor M. Yost
Florida Bar No. 1003178
J. Coy Stull
Florida Bar No. 15764
4221 W. Boy Scout Blvd., Suite 1000
Tampa, Florida 33607-5780
Tel. No.: (813) 229-4395
Fax No.: (813) 229-4133
Email: eyost@carltonfields.com
Email: jstull@carltonfields.com

Daniel C. Johnson
Florida Bar No. 522880
200 S. Orange Avenue, Suite 1000
Orlando, Florida 32801-3456
Tel. No.: (407) 849-0300
Fax No.: (407) 648-9099
Email: djohnson@carltonfields.com
Secondary: dcarlucci@carltonfields.com
Secondary: orlecf@cfdom.net

-and-

TAFT, STETTINIUS & HOLLISTER LLP
Andrew M. Alul (*pro hac vice* motion to be filed)
(Lead Counsel)
Roshan P. Shrestha, Ph.D. (*pro hac vice* motion to be filed)

111 East Wacker Drive, Suite 2800
Chicago, IL 60601
Tel. No.: 312-527-4000
Email: aalul@taftlaw.com
Email: rshrestha@taftlaw.com

Attorneys for Proposed Intervenor-Defendant Bionpharma Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above document has been furnished, electronically, through the CM/ECF system, to all counsel of record, and via email, noted above, to counsel at TAFT, STETTINIUS & HOLLISTER LLP, and via mail to:

Kristina Hanson
Wilson Sonsini Goodrich and Rosati
Suite 3300
One Market Plaza
Spear Tower
San Francisco, CA 94150

Wendy Devine
Wilson Sonsini Goodrich and Rosati
One Market Plaza
SpearnTower, Suite 3300
San Francisco, CA 94150

on this December 10, 2021.

/s/Eleanor M. Yost
Eleanor M. Yost

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

AZURITY PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	Case No. 8:21-cv-2515-TPB-SPF
CORERX, INC.,	)	
Defendant,	)	
v.	)	
BIONPHARMA INC.,	)	
Intervenor-Defendant	)	

[PROPOSED] INTERVENOR-DEFENDANT BIONPHARMA INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS IN INTERVENTION

Intervenor-Defendant Bionpharma Inc. ("Bionpharma") by its undersigned counsel, for its Answer, Defenses, and Counterclaims to the Complaint for Patent Infringement (D.I. 1, "Complaint") filed by Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity" or "Plaintiff"), states as follows:

ANSWER

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Bionpharma denies all allegations in Plaintiff's Complaint except those specifically admitted below:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 11,040,023 (the "'023 patent") and 11,141,405 the "'405 patent") (collectively the "Patents-in-Suit") and damages under the patent laws of the United States, Title 35, United States Code, that arises out of CoreRx's manufacture, use, sale, importation, and/or offer to sell and/or inducement of or contributing to others to do the foregoing within the United States of the product that is the subject of Bionpharma Inc.'s ("Bionpharma") ANDA No. 212408 ("CoreRx Formulation") prior to the expiration of the Patents-in-Suit. Azurity seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and any other applicable laws for CoreRx's infringement of the Patents-in-Suit.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that Azurity's Complaint purports to state an action for infringement of U.S. Patent Nos. 11,040,023 (the "'023 patent") and 11,141,405 the "'405 patent") under Title 35 of the United States Code based on certain activities by Defendant CoreRx, Inc. ("CoreRx") with respect to the product that is the subject of Bionpharma's Abbreviated New Drug Application ("ANDA") No. 212408 ("Bionpharma's ANDA") concerning a 1 mg/mL enalapril maleate oral solution described therein ("Bionpharma's ANDA product"). Bionpharma denies all remaining allegations of paragraph 1.

THE PARTIES

2. Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn MA 01801.

ANSWER: Bionpharma lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 2, and on that basis denies these allegations.

3. On information and belief, CoreRx is a corporation organized and existing under the laws of the State of Florida, with its principal place of business at 14205 Myerlake Cir., Clearwater, FL 33760. On information and belief, CoreRx is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the U.S. market.

ANSWER: Bionpharma lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 3, and on that basis denies these allegations.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, et seq., and from CoreRx's manufacture, use, sale, importation, and/or offer to sell and/or inducement of or contributing to others to do the foregoing within the United States of the CoreRx Formulation before the expiration of the Patents-in-Suit.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

5. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338(a) (patent infringement). Relief is sought under 35 U.S.C. §§ 271(a)-(c).

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

6. This Court has personal jurisdiction over CoreRx because, among other things, on information and belief, CoreRx is a corporation formed under the laws of the State of Florida that maintains a principal place of business in Florida.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma is without sufficient information with which to admit or deny the allegations of Paragraph 6, and therefore denies the allegations of this Paragraph.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

AZURITY'S EPANED® PRODUCT

8. Azurity holds approved NDA No. 208686 for a ready-to-use oral solution of enalapril maleate, which is prescribed and sold under the trade name Epaned®.

ANSWER: Bionpharma lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 8, and on that basis denies these allegations.

9. Azurity's Epaned® product is the first FDA approved and labeled ace inhibitor treatment that is a ready-to-use oral solution for hypertension in children under six years of age. Epaned® is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

ANSWER: Denied.

PATENTS-IN-SUIT

10. The ’023 patent, entitled “Enalapril Formulations,” issued on June 22, 2021. A true and correct copy of the ’023 patent is attached to this Complaint as Exhibit A.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that what purports to be a copy of the ’023 patent is attached to the Complaint as Exhibit A; that the ’023 patent is entitled “Enalapril Formulations” and bears an issue date of June 22, 2021. Bionpharma denies any suggestion that the ’023 patent is valid or enforceable. Bionpharma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in paragraph 10, and on that basis denies these allegations.

11. The ’023 patent was duly and legally issued to Azurity as the assignee and Azurity owns all rights, title, and interest in the ’023 patent.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

12. Pursuant to 21 U.S.C. § 355, the ’023 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with Azurity’s Epaned® product.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, admitted.

13. The ’023 patent describes stable, oral liquid formulations of enalapril.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

14. The ’023 patent expires on March 25, 2036.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

15. The ’405 patent, entitled “Enalapril Formulations,” issued on October 12, 2021. A true and correct copy of the ’405 patent is attached to this Complaint as Exhibit B.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that what purports to be a copy of the ’405 patent is attached to the Complaint as Exhibit B; that the ’405 patent is entitled “Enalapril Formulations” and bears an issue date of October 12, 2021. Bionpharma denies any suggestion that the ’405 patent is valid or enforceable. Bionpharma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in paragraph 15, and on that basis denies these allegations.

16. The ’405 patent was duly and legally issued to Azurity as the assignee and Azurity owns all rights, title, and interest in the ’405 patent.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

17. Pursuant to 21 U.S.C. § 355, the ’405 patent is listed in the Orange Book in connection with Azurity’s Epaned® product.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, admitted.

18. The ’405 patent describes stable, oral liquid formulations of enalapril.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

19. The ’405 patent expires on March 25, 2036.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

[ALLEGED] INFRINGEMENT BY CORERX

20. On information and belief, CoreRx developed, manufactures, and sells the CoreRx Formulation.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that CoreRx, in collaboration with Bionpharma, developed Bionpharma’s ANDA product, and that CoreRx manufactures and supplies Bionpharma’s ANDA product. Bionpharma denies all remaining allegations of Paragraph 20.

21. On June 22, 2021, Azurity brought an action against Bionpharma alleging that the filing of ANDA No. 212408 was an act of infringement of the ’023 patent because the CoreRx Formulation is covered by one or more claims in the ’023 patent. That case is captioned *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.) (“the ’023 Bionpharma Action”).

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits

that Azurity instituted *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.) ("the '023 Bionpharma Action") against Bionpharma. Bionpharma denies all remaining allegations of Paragraph 21.

22. During prior litigation regarding ANDA No. 212408, CoreRx was represented by the same counsel that represented Bionpharma. *See Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 18-1962-LPS, D.I. 56 (D. Del. Mar. 13, 2020) & C.A. No. 19-1067-LPS, D.I. 68 (D. Del. Mar. 13, 2020).

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, admitted.

23. On information and belief, CoreRx is aware of the '023 Bionpharma Action.

ANSWER: Bionpharma is without sufficient information with which to form a belief as to the allegations of Paragraph 23, and therefore denies those allegations.

24. On information and belief, CoreRx is aware that Azurity, in the '023 Bionpharma Action, filed a motion for preliminary injunction ("Azurity's PI Motion") seeking to enjoin the sale of the CoreRx Formulation.

ANSWER: Bionpharma is without sufficient information with which to form a belief as to the allegations of Paragraph 24, and therefore denies those allegations.

25. On information and belief, CoreRx is aware that Bionpharma, in response to Azurity's PI Motion, does not deny that the CoreRx Formulation infringes several claims of the '023 patent.

ANSWER: Denied.

26. On October 15, 2021, Azurity brought an action against Bionpharma for infringement of the '405 patent. That case is captioned *Azurity*

Pharmaceuticals, Inc. v. Bionpharma Inc., C.A. No. 21-1455-LPS (D. Del.) ("the '405 Bionpharma Action").

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that Azurity instituted *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1455-LPS (D. Del.) ("the '405 Bionpharma Action") against Bionpharma. Bionpharma denies all remaining allegations of Paragraph 26.

27. On information and belief, CoreRx is aware of the '405 Bionpharma Action.

ANSWER: Bionpharma is without sufficient information with which to form a belief as to the allegations of Paragraph 27, and therefore denies those allegations.

28. The Patents-in-Suit expire on March 25, 2036.

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied.

29. On information and belief, on August 10, 2021, several weeks after the '023 patent legally issued from the United States Patent and Trademark Office and Azurity brought suit for infringement of the '023 patent against Bionpharma, ANDA No. 212408 was approved by FDA. Thereafter, in blatant disregard for Azurity's patent rights, Bionpharma began offering for sale and selling the CoreRx Formulation which, on information and belief, was manufactured by CoreRx.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits its ANDA was approved by FDA and that it began selling its ANDA product, which

is supplied by CoreRx. Bionpharma denies all remaining allegations of Paragraph 29.

30. On information and belief, CoreRx has and continues to engage in the commercial manufacture and sale of the CoreRx Formulation before the expiration of the Patents-in-Suit with the knowledge and intent to infringe the Patents-in-Suit.

ANSWER: Denied.

31. On information and belief, the CoreRx Formulation infringes at least one claim of the Patents-in-Suit, including at least claim 1 of the '023 patent and claim 1 of the '405 patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

32. On information and belief, under 35 U.S.C. § 271(a)-(c), CoreRx has knowingly, willfully, repeatedly, and continually infringed at least one claim of the Patents-in-Suit, including at least claim 1 of the '023 patent and claim 1 of the '405 patent, by manufacturing, using, offering for sale, selling, and/or importing the CoreRx Formulation, and/or inducement of or contributing to others to do the foregoing in the United States before the expiration date of the Patents-in-Suit.

ANSWER: Denied.

CLAIMS FOR RELIEF

Count I—[Alleged] Infringement of the '023 Patent under 35 U.S.C. § 271(a)-(c)

33. Azurity realleges and incorporates paragraphs 1 through 32 as if fully set forth herein.

ANSWER: Bionpharma incorporates its answers to paragraphs 1 through 32 as if fully set forth herein.

34. On information and belief, the CoreRx Formulation has received final approval from FDA.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that its ANDA has been approved by FDA. Bionpharma denies all remaining allegations of Paragraph 34.

35. On information and belief, CoreRx has engaged in and/or induced and continues to induce another, including Bionpharma, to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation. CoreRx's acts of infringement have irreparably injured and damaged and continue to irreparably injure and damage Azurity.

ANSWER: Denied.

36. The commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation is an act of direct infringement of one or more claims of the '023 patent under 35 U.S.C. § 271(a), including at least claim 1 of the '023 patent.

ANSWER: Denied.

37. On information and belief, CoreRx is inducing infringement of one or more claims of the '023 patent under 35 U.S.C. § 271(b) by inducing the making, using, offering to sell, selling, and/or importation of the CoreRx Formulation in the United States. On information and belief, CoreRx is intentionally encouraging acts of direct infringement with knowledge of the '023 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

38. On information and belief, CoreRx is contributorily infringing one or more claims of the '023 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the CoreRx Formulation in the United States. On information and belief, CoreRx,

through offering to sell or selling the CoreRx Formulation, has offered to sell or sold, and continues to do so, within the United States or import into the United States a component of a composition or material for use in practicing one or more claims of the ’023 patent. On information and belief, CoreRx conducts and has conducted such activities knowing such component of a composition or material to be especially adapted for a use that infringes one or more claims of the ’023 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

ANSWER: Denied.

39. The foregoing actions by CoreRx constitute infringement of the ’023 patent.

ANSWER: Denied.

40. CoreRx is committing those acts of infringement without license or authorization.

ANSWER: Denied.

41. CoreRx is committing those acts of infringement despite its knowledge of both the ’023 patent and the ’023 Bionpharma Action.

ANSWER: Denied.

42. Azurity is entitled to a judgement that the commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation infringes the ’023 patent.

ANSWER: Denied.

43. Azurity has suffered and will continue to suffer financial harm as a result of CoreRx’s infringing activities.

ANSWER: Denied.

44. The commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation in violation of Azurity’s patent

rights has caused and is continuing to cause substantial and irreparable harm to Azurity for which damages are inadequate.

ANSWER: Denied.

45. Azurity is entitled to monetary damages but, because the infringement by CoreRx of the '023 patent will continue to cause Azurity irreparable injury and damage for which there is no adequate remedy at law unless and until CoreRx is enjoined from infringing the '023 patent, Azurity has no complete, adequate remedy at law and, therefore, is entitled to injunctive relief.

ANSWER: Denied.

Count II—[Alleged] Infringement of the '405 Patent under 35 U.S.C. § 271(a)-(c))

46. Azurity realleges and incorporates paragraphs 1 through 32 as if fully set forth herein.

ANSWER: Bionpharma incorporates its answers to paragraphs 1 through 32 as if fully set forth herein.

47. On information and belief, the CoreRx Formulation has received final approval from FDA.

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that its ANDA has been approved by FDA. Bionpharma denies all remaining allegations of Paragraph 47.

48. On information and belief, CoreRx has engaged in and/or induced and continues to induce another, including Bionpharma, to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation. CoreRx's acts of infringement have irreparably injured and damaged and continue to irreparably injure and damage Azurity.

ANSWER: Denied.

49. The commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation is an act of direct infringement of one or more claims of the '405 patent under 35 U.S.C. § 271(a), including at least claim 1 of the '405 patent.

ANSWER: Denied.

50. On information and belief, CoreRx is inducing infringement of one or more claims of the '405 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the CoreRx Formulation in the United States. On information and belief, CoreRx is intentionally encouraging acts of direct infringement with knowledge of the '405 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

51. On information and belief, CoreRx is contributorily infringing one or more claims of the '405 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the CoreRx Formulation in the United States. On information and belief, CoreRx, through offering to sell or selling the CoreRx Formulation, has offered to sell or sold, and continues to do so, within the United States or import into the United States a component of a composition or material for use in practicing one or more claims of the '405 patent. On information and belief, CoreRx conducts and has conducted such activities knowing such component of a composition or material to be especially adapted for a use that infringes one or more claims of the '405 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

ANSWER: Denied.

52. The foregoing actions by CoreRx constitute infringement of the '405 patent.

ANSWER: Denied.

53. CoreRx is committing those acts of infringement without license or authorization.

ANSWER: Denied.

54. CoreRx is committing those acts of infringement despite its knowledge of both the ’405 patent and the ’405 Bionpharma Action Azurity is entitled to a judgement that the commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation infringes the ’405 patent.

ANSWER: Denied.

55. Azurity has suffered and will continue to suffer financial harm as a result of CoreRx’s infringing activities.

ANSWER: Denied.

56. The commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation in violation of Azurity’s patent rights has caused and is continuing to cause substantial and irreparable harm to Azurity for which damages are inadequate.

ANSWER: Denied.

57. Azurity is entitled to monetary damages but, because the infringement by CoreRx of the ’405 patent will continue to cause Azurity irreparable injury and damage for which there is no adequate remedy at law unless and until CoreRx is enjoined from infringing the ’405 patent, Azurity has no complete, adequate remedy at law and, therefore, is entitled to injunctive relief.

ANSWER: Denied.

PRAYER FOR RELIEF

Azurity respectfully requests the following relief:

a) A finding that the Patents-in-Suit are valid and enforceable;

b) A judgment that CoreRx's making, using, offering to sell, or selling in the United States, or importing into the United States of the CoreRx Formulation directly infringes one or more claims of the Patents-in-Suit;

c) A judgment that CoreRx has induced infringement of the Patents-in-Suit by encouraging others to use, sell, offer for sale, and/or import the CoreRx Formulation in the United States before the expiration of the Patents-in-Suit;

d) A judgment that CoreRx has contributorily infringed the Patents-in-Suit by offering to sell or selling the CoreRx Formulation in the United States before the expiration of the Patents-in-Suit, knowing the same is especially adapted for a use that directly infringes the Patents-in-Suit and that there is no substantial non-infringing use for the CoreRx Formulation;

e) A judgment that CoreRx's infringement was and is willful;

f) A finding that Azurity be awarded all damages adequate to compensate it for CoreRx's past infringement and any continuing or future infringement of the Patents-in-Suit in addition to interest and costs;

g) A permanent injunction enjoining CoreRx, and its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture use, offer to sell, or importation into the United States, of any drug product covered by the Patents-in-Suit, including the CoreRx Formulation, until the expiration of the Patents-in-Suit;

h) A finding that CoreRx's infringement is willful and that the monetary damages awarded to Azurity be trebled and include pre- and post-judgment interest, costs, and disbursements pursuant to 35 U.S.C. § 284;

i) A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285, and that CoreRx is responsible for payment of Azurity's attorneys' fees and costs;

j) An award of any such other and further relief as the Court may deem just and proper.

ANSWER: Bionpharma denies Azurity is entitled to any of the relief requested in their Prayer for Relief or otherwise.

BIONPHARMA'S ADDITIONAL DEFENSES

Bionpharma asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST DEFENSE
(INVALIDITY OF THE '023 PATENT)

The claims of the '023 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation for at least the reasons set forth in Bionpharma's counterclaim Count I.

SECOND DEFENSE
(NO INFRINGEMENT OF THE '023 PATENT)

The manufacture, use, offer for sale, sale, or importation of Bionpharma's ANDA product does not and will not infringe, either literally or under the doctrine of equivalents, either directly or indirectly, any valid and enforceable claim of the '023 patent for at least the reasons set forth in Bionpharma's counterclaim Count II.

THRID DEFENSE
(INVALIDITY OF THE '405 PATENT)

The claims of the '405 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation for at least the reasons set forth in Bionpharma's counterclaim Count III.

FOURTH DEFENSE
(NO INFRINGEMENT OF THE '405 PATENT)

The manufacture, use, offer for sale, sale, or importation of Bionpharma's ANDA product does not and will not infringe, either literally or under the doctrine of equivalents, either directly or indirectly, any valid and enforceable claim of the '482 patent for at least the reasons set forth in Bionpharma's counterclaim Count IV.

FIFTH DEFENSE
(FAILURE TO STATE A CLAIM)

Azurity's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

SIXTH AFFIRMATIVE DEFENSE
(*RES JUDICATA*; COLLATERAL ESTOPPEL)

Azurity's Complaint is barred on *res judicata* grounds, including on claim preclusion grounds as Azurity's Complaint asserts the same cause of action that was previously litigated and resolved in Bionpharma's favor in *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.), including on claim preclusion grounds because Azurity has voluntarily twice dismissed the same causes of action against CoreRx, and including on collateral estoppel grounds.

SEVENTH AFFIRMATIVE DEFENSE
(DISCLOSURE-DEDICATION)

Plaintiff is legally barred from asserting infringement of certain claims of the

'023 and '405 patents under the disclosure-dedication doctrine.

EIGHTH DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

This Court lacks subject matter jurisdiction over the claims in Azurity's Complaint, as those claims fail to state a case or controversy between Azurity and CoreRx.

***

WHEREFORE, Bionpharma requests the Court enter judgment in its favor, award Bionpharma its attorneys' fees, costs of this action, and such other and further relief as the Court deems proper.

BIONPHARMA'S COUNTERCLAIMS

Pursuant to Fed. R. Civ. P. 13 and 24, Intervenor-Defendant Bionpharma Inc. ("Bionpharma") hereby states for its Counterclaims against Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity"), the following:

PARTIES

1. Bionpharma is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 600 Alexander Rd., #2-4B, Princeton, NJ 08540. Bionpharma is in the business of, among other things, selling pharmaceutical drug products, including pharmaceutical drug products that Bionpharma has contracted with third parties to develop and supply, such as Defendant CoreRx, Inc. ("CoreRx"), a contract development and manufacturing organization ("CDMO").

2. Upon information and belief, Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801. Upon information and belief, Azurity is the successor-in-interest to Silvergate Pharmaceuticals, Inc.

NATURE OF THE ACTION

3. Bionpharma brings this action for a declaratory judgment that U.S. Patent Nos. 11,040,023 ("'023 patent") and 11,141,405 ("'405 patent") (together,

"the patents-in-suit"), which Azurity asserts in the instant suit against CoreRx, are invalid and not infringed.

JURISDICTION, VENUE, AND CONDITIONS PRECEDENT

4. These claims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331 and 1338(a); and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has subject matter jurisdiction over these claims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Bionpharma and Azurity arising under the Patent Laws of the United States, 35 U.S.C. § 1, et seq.

7. This Court has personal jurisdiction over Azurity based on, *inter alia*, the filing of this lawsuit in this jurisdiction.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

9. All conditions precedent to this lawsuit have occurred, been satisfied, or been waived.

10. Bionpharma has retained the below listed counsel to represent it in the case, and agreed to pay counsel a reasonable fee for their services.

FACTS COMMON TO ALL COUNTS

11. On or about June 22, 2021, the United States Patent and Trademark Office issued the ’023 patent.

12. Upon information and belief, Azurity is the assignee of the ’023 patent.

13. On or about October 12, 2021, the United States Patent and Trademark Office issued the ’405 patent.

14. Upon information and belief, Azurity is the assignee of the ’405 patent.

15. Azurity purports and claims to have the right to enforce the ’023 and ’405 patents.

16. In 2016, Bionpharma contracted with CoreRx to, in collaboration with Bionpharma, develop a 1 mg/mL enalapril maleate oral solution as generic to Azurity’s Epaned® (enalapril maleate) oral solution, 1 mg/mL, and to commercially manufacture that product for Bionpharma.

17. In 2018, Bionpharma prepared and filed with the U.S. Food and Drug Administration (“FDA”) Abbreviated New Drug Application (“ANDA”) No. 212408, which sought FDA approval for the 1 mg/mL enalapril oral solution product that CoreRx had collaboratively developed with Bionpharma (“Bionpharma’s ANDA”).

18. Bionpharma's ANDA was approved by FDA on or about August 10, 2021, and Bionpharma commercially and lawfully launched its ANDA product on or about August 17, 2021.

19. Pursuant to a Master Manufacturing Supply Agreement effective November 2020 ("MMSA"), CoreRx commercially manufactures and supplies Bionpharma's ANDA product.

20. On information and belief, on or about March 26, 2018, NovaQuest Capital Management ("NovaQuest"), an investment or venture capital firm, acquired a controlling interest in Azurity.

21. On information and belief, on or about January 19, 2021, NovaQuest acquired a controlling interest in CoreRx.

22. On information and belief, NovaQuest controls and/or dominates Azurity through an intermediate holding company, CutisPharma Intermediate Holdings Inc.

23. On information and belief, NovaQuest controls and/or dominates CoreRx through an intermediate holding company, CutisPharma Intermediate Holdings Inc.

24. On or about October 27, 2021, Azurity instituted this action against CoreRx, alleging, *inter alia*, that "CoreRx's manufacture, use, sale, importation, and/or offer to sell and/or inducement of or contributing to others to do the foregoing

within the United States of the product that is the subject of [Bionpharma's] ANDA . . . prior to the expiration of the [p]atents-in-[s]uit" infringes the patents-in-suit. D.I. 1, Compl. ¶ 1.

25. Bionpharma has an interest in the subject matter of the instant action; namely, CoreRx's manufacture and supply of Bionpharma's ANDA product.

26. Disposal of the instant action without Bionpharma's participation would impair or impede Bionpharma's ability to protect its interest in the subject matter of this action.

27. Because of the common ownership between Azurity and CoreRx, Bionpharma has a reasonable belief that CoreRx may not adequately represent Bionpharma's interest in the subject matter of this action.

28. On or about November 11, 2021, Azurity filed a First Amended and Supplemental Complaint for Patent Infringement in the United States District Court for the District of Delaware in *Azurity Pharmaceuticals, Inc. v. Bionpharma, Inc.*, C.A. No. 21-1286-LPS (D. Del.) (D.I. 89) alleging, *inter alia,* that Bionpharma's commercial marketing of its ANDA product directly and indirectly infringes the '023 patent.

29. On or about October 15, 2021, Azurity filed a Complaint for Patent Infringement in the United States District Court for the District of Delaware in *Azurity Pharmaceuticals, Inc. v. Bionpharma, Inc.*, C.A. No. 21-1455-LPS (D. Del.)

alleging, *inter alia*, that Bionpharma's commercial marketing of its ANDA product directly and indirectly infringes the '405 patent.

COUNT I
(Declaratory Judgment of Invalidity of the '023 Patent)

30. Bionpharma realleges and incorporates by reference the allegations of paragraphs 1-29 as though fully set forth herein.

31. There is an actual, substantial, and continuing case or controversy between Bionpharma and the Azurity regarding, *inter alia*, the invalidity of the '023 patent.

32. The claims of the '023 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

33. Claim 1 of the '023 patent, the sole independent claim, recites as follows:

> 1. A stable oral liquid formulation, consisting essentially of:
>
> (i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
>
> (ii) a sweetener;
>
> (iii) a preservative, wherein the preservative comprises sodium benzoate, a paraben or a mixture of parabens;
>
> (iv) water; and
>
> (v) optionally a flavoring agent;

wherein the formulation is stable at about 5±3° C. for at least 12 months; and wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

34. The specification of the ’023 patent does not contain a written description of the subject matter claimed in the ’023 patent, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use the same. Specifically, nowhere in the specification of the ’023 patent is there any description of an enalapril liquid without a buffer, including an enalapril liquid without a buffer that would meet the stability limitations recited in the claims. Moreover, Azurity argued during the prosecution history of the ’023 patent, and in connection with *Silvergate Pharmaceuticals, Inc. v. Bionpharma, Inc.*, Nos. 18-1062-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.), that the stability of enalapril oral liquid formulations was unpredictable and that only through preparation and testing of formulations could a person of ordinary skill ascertain what combination of ingredients would lead to stable formulations. There is nothing in the specification of the ’023 patent demonstrating to a person of ordinary skill in the art that the named inventors were in possession of the claimed enalapril oral liquid formulations as of the filing date of the application that issued into the ’023 patent, and the claims of the ’023 patent are therefore invalid for lack of written description.

35. The claims of the ’023 patent are also invalid for lack of enablement, as the ’023 patent specification does not describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation. Specifically, nowhere in the specification of the ’023 patent is there any data provided or rationale advanced demonstrating that the claimed enalapril oral liquid formulations, some of which do not include buffers, would be stable at refrigerated conditions for the storage periods recited in the claims. Moreover, Azurity argued during the prosecution history of the ’023 patent, and in connection with *Silvergate Pharmaceuticals, Inc. v. Bionpharma, Inc.*, Nos. 18-1062-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.), that the stability of enalapril oral liquid formulations was unpredictable and that only through preparation and testing of formulations could a person of ordinary skill ascertain what combination of ingredients would lead to stable formulations. It would require undue experimentation, including the preparation and testing for 12 months or longer of potentially tens of thousands of enalapril oral liquid formulations, for a person of skill in the art to determine what formulations meet the recited stability requirements and thus fall within the scope of the claims of the ’023 patent.

36. The claims of the ’023 patent are also obvious and therefore invalid under 35 U.S.C. § 103 over the following references, which disclose each element

of the claims of the '023 patent: (1) the 2014 Prescribing Information for the Epaned® Kit; (2) Ip and Brenner, 16 ANALYTICAL PROFILES OF DRUG SUBSTANCES 207, 236 (1987); (3) Raymond C. Rowe et al., HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 605-610 (6th Ed. 2009); (4) U.S. Food and Drug Administration, *Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products* (Nov. 2003, Rev. 2; and (5) U.S. Patent No. 8,568,747 B1. A POSA would be motivated to combine these references to formulate a ready-to-use enalapril liquid formulation that is stable for at least 12 months under refrigerated conditions, to overcome the problems associated with prior art enalapril liquid formulations, such as the Epaned® Kit, including lack of long-term stability. There are no secondary considerations of non-obviousness that have a nexus to the '023 patent claims and that are commensurate in scope with those claims.

37. Bionpharma is entitled to a judicial declaration that the claims of the '023 patent are invalid.

COUNT II
(Declaratory Judgment of Non-Infringement of the '023 Patent)

38. Bionpharma realleges and incorporates by reference the allegations of paragraphs 1-29 as though fully set forth herein.

39. There is an actual, substantial, and continuing case or controversy between Bionpharma and the Azurity regarding, *inter alia*, non-infringement of the claims of the '023 patent.

40. Bionpharma's ANDA, and the manufacture, use, offer for sale, sale, importation, and/or marketing of Bionpharma's ANDA product, has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '023 patent, either literally or under the doctrine of equivalents. For instance, any claim from Azurity that Bionpharma's ANDA product infringes the '023 patent are barred on claim preclusion grounds, as such a claim would assert the same cause of action previously litigated and resolved in Bionpharma's favor in connection with *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.). Furthermore, certain claims of the '023 patent require sodium benzoate as a preservative, such as '023 patent claims 17, 18, and 20; Bionpharma's ANDA product does not contain sodium benzoate. Furthermore, Bionpharma has a license to the patents-in-suit under the MMSA, and any patent rights that Azurity may have had in Bionpharma's ANDA have been exhausted and/or extinguished by the first sale doctrine.

41. Bionpharma is entitled to a judicial declaration that the filing of its ANDA, and the manufacture, use, offer for sale, sale, importation, and/or marketing of Bionpharma's ANDA product has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '023 patent, either literally or under the doctrine of equivalents.

COUNT III
(Declaratory Judgment of Invalidity of the '405 Patent)

42. Bionpharma realleges and incorporates by reference the allegations of paragraphs 1-29 as though fully set forth herein.

43. There is an actual, substantial, and continuing case or controversy between Bionpharma and the Azurity regarding, *inter alia*, the invalidity of the '405 patent.

44. The claims of the '405 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

45. Claims 1 and 13 of the '405 patent, the only independent claims, recite as follows:

> 1. A stable oral liquid formulation, consisting essentially of: (i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
>
> (ii) a preservative, wherein the preservative is sodium benzoate, ascorbic acid, ascorbyl palmitate, BHA, BHT, EDTA and its salts, erythorbic acid, fumaric acid, malic acid, propyl gallate, sodium ascorbate, sodium bisulfate, sodium metabisulfite, sodium sulfite, benzoic acid, potassium sorbate, vanillin, a paraben, or a mixture of parabens; and
>
> (iii) water;
>
> wherein the formulation optionally comprises a buffer to maintain the pH about 4.5 or below, a sweetener, a flavoring agent, or any combination thereof;

wherein the formulation is stable at about 5±3° C. for at least 12 months; and wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

13. A stable oral liquid formulation, consisting essentially of:

(i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;

(ii) a preservative, wherein the preservative is sodium benzoate, ascorbic acid, ascorbyl palmitate, BHA, BHT, EDTA and its salts, erythorbic acid, fumaric acid, malic acid, propyl gallate, sodium ascorbate, sodium bisulfate, sodium metabisulfite, sodium sulfite, benzoic acid, potassium sorbate, vanillin, a paraben, or a mixture of parabens; and

(iii) water;

wherein the formulation optionally comprises a buffer that is present in the formulation at a concentration of up to 20 mM, a sweetener, a flavoring agent, or any combination thereof;

wherein the formulation is stable at about 5±3° C. for at least 12 months; and wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

46. The specification of the ’405 patent does not contain a written description of the subject matter claimed in the ’405 patent, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use the same. Specifically, nowhere in the specification of the ’405 patent is there any description of an enalapril liquid without a buffer, including an enalapril liquid without a buffer

that would meet the stability limitations recited in the claims. Moreover, Azurity argued during the prosecution history of the '405 patent, and in connection with *Silvergate Pharmaceuticals, Inc. v. Bionpharma, Inc.*, Nos. 18-1062-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.), that the stability of enalapril oral liquid formulations was unpredictable and that only through preparation and testing of formulations could a person of ordinary skill ascertain what combination of ingredients would lead to stable formulations. There is nothing in the specification of the '405 patent demonstrating to a person of ordinary skill in the art that the named inventors were in possession of the claimed enalapril oral liquid formulations as of the filing date of the application that issued into the '405 patent, and the claims of the '405 patent are therefore invalid for lack of written description.

47. The claims of the '405 patent are also invalid for lack of enablement, as the '405 patent specification does not describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation. Specifically, nowhere in the specification of the '405 patent is there any data provided or rationale advanced demonstrating that the claimed enalapril oral liquid formulations, some of which do not include buffers, would be stable at refrigerated conditions for the storage periods recited in the claims. Moreover, Azurity argued during the prosecution history of the '405 patent, and in connection with *Silvergate*

Pharmaceuticals, Inc. v. Bionpharma, Inc., Nos. 18-1062-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.), that the stability of enalapril oral liquid formulations was unpredictable and that only through preparation and testing of formulations could a person of ordinary skill ascertain what combination of ingredients would lead to stable formulations. It would require undue experimentation, including the preparation and testing for 12 months or longer of potentially tens of thousands of enalapril oral liquid formulations, for a person of skill in the art to determine what formulations meet the recited stability requirements and thus fall within the scope of the claims of the '405 patent.

48. The claims of the '405 patent are also obvious and therefore invalid under 35 U.S.C. § 103 over the following references, which disclose each element of the claims of the '405 patent: (1) the 2014 Prescribing Information for the Epaned® Kit; (2) Ip and Brenner, 16 ANALYTICAL PROFILES OF DRUG SUBSTANCES 207, 236 (1987); (3) Raymond C. Rowe et al., HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 605-610 (6th Ed. 2009); (4) U.S. Food and Drug Administration, *Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products* (Nov. 2003, Rev. 2; and (5) U.S. Patent No. 8,568,747 B1. A POSA would be motivated to combine these references to formulate a ready-to-use enalapril liquid formulation that is stable for at least 12 months under refrigerated conditions, to overcome the problems associated with prior art enalapril liquid formulations, such

as the Epaned® Kit, including lack of long-term stability. There are no secondary considerations of non-obviousness that have a nexus to the '405 patent claims and that are commensurate in scope with those claims.

49. Bionpharma is entitled to a judicial declaration that the claims of the '405 patent are invalid.

COUNT IV
(Declaratory Judgment of Non-Infringement of the '405 Patent)

50. Bionpharma realleges and incorporates by reference the allegations of paragraphs 1-29 as though fully set forth herein.

51. There is an actual, substantial, and continuing case or controversy between Bionpharma and the Azurity regarding, *inter alia*, non-infringement of the claims of the '405 patent.

52. Bionpharma's ANDA, and the manufacture, use, offer for sale, sale, importation, and/or marketing of Bionpharma's ANDA product, has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '405 patent, either literally or under the doctrine of equivalents. For instance, any claim from Azurity that Bionpharma's ANDA product infringes the '405 patent are barred on claim preclusion grounds, as such a claim would assert the same cause of action previously litigated and resolved in Bionpharma's favor in connection with *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-LPS, 19-1067-LPS, and 20-1256-LPS (D.

Del.). Furthermore, certain claims of the '405 patent require sodium benzoate as a preservative, such as '405 patent claims 9 and 18; Bionpharma's ANDA product does not contain sodium benzoate. Furthermore, Bionpharma has a license to the patents-in-suit under the MMSA, and any patent rights that Azurity may have had in Bionpharma's ANDA have been exhausted and/or extinguished by the first sale doctrine.

53. Bionpharma is entitled to a judicial declaration that the filing of its ANDA, and the manufacture, use, offer for sale, sale, importation, and/or marketing of Bionpharma's ANDA product has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '405 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Bionpharma respectfully prays for judgment in its favor and against Azurity:

a) Declaring that the claims of the '023 patent are invalid;

b) Declaring that the claims of the '405 patent are invalid;

c) Declaring that the filing of Bionpharma's ANDA, and the manufacture, use, sale, offer for sale, importation, and/or marketing of Bionpharma's ANDA product has not infringed, does not infringe, and will not

infringe, either directly or indirectly, any valid and/or enforceable claim of the ’023 patent either literally or under the doctrine of equivalents;

d) Declaring that the filing of Bionpharma’s ANDA, and the manufacture, use, sale, offer for sale, importation, and/or marketing of Bionpharma’s ANDA product has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid and/or enforceable claim of the ’405 patent either literally or under the doctrine of equivalents

e) Ordering that Azurity’s Complaint for Patent Infringement be dismissed with prejudice and judgment entered in favor of Bionpharma and CoreRx;

f) Declaring this case exceptional and awarding Bionpharma its reasonable attorneys’ fees and costs under 35 U.S.C. § 285; and

g) Awarding such other and further relief as the Court may deem just and proper.

Dated: [EXHIBIT A]

Respectfully submitted,

CARLTON FIELDS, P.A.

By: [EXHIBIT A]
Eleanor M. Yost
Florida Bar No. 1003178
J. Coy Stull
Florida Bar No. 15764

4221 W. Boy Scout Blvd., Suite 1000
Tampa, Florida 33607-5780
Tel. No.: (813) 229-4395
Fax No.: (813) 229-4133
Email: eyost@carltonfields.com
Email: jstull@carltonfields.com

Daniel C. Johnson
Florida Bar No. 522880
200 S. Orange Avenue, Suite 1000
Orlando, Florida 32801-3456
Tel. No.: (407) 849-0300
Fax No.: (407) 648-9099
Email: djohnson@carltonfields.com
Secondary: dcarlucci@carltonfields.com
Secondary: orlecf@cfdom.net

-and-

TAFT, STETTINIUS & HOLLISTER LLP
Andrew M. Alul (*pro hac vice* motion to be filed)
(Lead Counsel)
Roshan P. Shrestha, Ph.D. (*pro hac vice* motion to be filed)
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
Tel. No.: 312-527-4000
Email: aalul@taftlaw.com
Email: rshrestha@taftlaw.com

Attorneys for [Proposed] Intervenor-Defendant Bionpharma Inc.

EXHIBIT B

M&A DEAL SUMMARY

NovaQuest Capital Management Acquires Azurity Pharmaceuticals

On March 26, 2018, private equity firm NovaQuest Capital Management acquired life science company Azurity Pharmaceuticals, Inc. from Ampersand Capital Partners

Acquisition Highlights

- This is NovaQuest Capital Management's 3rd transaction in the Life Science sector.
- This is NovaQuest Capital Management's 3rd transaction in the United States.
- This is NovaQuest Capital Management's 1st transaction in Massachusetts.

M&A DEAL SUMMARY

Date	2018-03-26
Target	Azurity Pharmaceuticals, Inc.
Sector	Life Science
Buyer(s)	NovaQuest Capital Management
Sellers(s)	Ampersand Capital Partners
Deal Type	Secondary Buyout
Advisor(s)	TAP Advisors LLC (Financial)

TARGET

BUYER(S) 1

Buyer	DESCRIPTION
NovaQuest Capital Management	NovaQuest Capital Management is a private equity firm focused on acquiring and investing in growth-stage middle-market healthcare companies. Specific areas of interest include life science, medical technology, healthcare/facility services, and healthcare focused IT. The Firm targets profitable companies valued up to $500 million with $20 to $100 million of revenue. NovaQuest Capital Management was established in 2000 and is based in Raleigh, North Carolina.

CATEGORY	Private Equity Firm
FOUNDED	2010
PE ASSETS	3.0B USD
SIZE	Large
TYPE	Sector Focused

Azurity Pharmaceuticals, Inc.

Woburn, Massachusetts, United States

Azurity Pharmaceuticals, Inc. is a privately held, specialty pharmaceutical company focusing on the development and commercialization of value-added proprietary drug products and technologies in the prescription compounding sector of the pharmaceutical industry. The company's product line and development efforts initially are focused on providing optimized, more efficient alternatives for the preparation of the nearly 10 million currently compounded prescriptions, by offering FIRST® Unit-of-Use Prescription Compounding Kits. Use of these branded compounding kits will be beneficial to all triad participants, namely physicians, pharmacists, and patients. Three U.S. patents have been issued to the Company with several additional patents pending.

DEAL STATS	#
Overall	3 of 10
Sector (Life Science)	3 of 6
Type (Secondary Buyout)	1 of 2
State (Massachusetts)	1 of 1
Country (United States)	3 of 9
Year (2018)	2 of 4

PREVIOUS DEAL

DATE	TARGET
2018-01-03	**Viamet Pharmaceuticals, Inc.** Durham, North Carolina, Unite **Viamet Pharmaceuticals, Inc. disco develops breakthrough therapies b leadership in metalloenzyme chemi biology. Company clinical portfolio**

FOLLOWING DEAL

DATE	TARGET
2018-05-14	**Clinical Ink, Inc.** Horsham, Pennsylvania, Unite **Clinical Ink is a clinical technology that offers data certainty from sour submission. The company's Lumer eSource clinical technology and…**

SELLER(S)

1

SELLER	DESCRIPTION
Ampersand Capital Partners Wellesley, Massachusetts, United States	**Ampersand Capital Partners is a middle-market private equity group that concentrates on growth equity investment opportunities in the healthcare sector. The Firm looks to invest $10 to $100 million in businesses with $10 to $100 million of revenue. Specific areas of interests within healthcare include lab products, specialty diagnostic equipment, pharmaceutical outsourcing, and specialty pharma.**

- & More

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CATEGORY	Growth Capital Firm
FOUNDED	1988
PE ASSETS	2.0B USD
SIZE	Large
TYPE	Sector Focused

Ampersand generally prefers to be the first and sole institutional investor. Ampersand was formed in 1988 and is based in Wellesley, Massachusetts.

DEAL STATS	#
Overall	36 of 44
Sector (Life Science)	14 of 19
Type (Secondary Buyout)	4 of 4
State (Massachusetts)	7 of 9
Country (United States)	36 of 44
Year (2018)	3 of 6

PREVIOUS DEAL

DATE	TARGET	D
2018-03-26	**MedPharm Ltd.** Surrey, United Kingdom MedPharm Ltd. is a global provider of contract topical and transdermal product design and formulation…	E

FOLLOWING DEAL

DATE	TARGET
2018-06-01	**Alcami Corp.** Durham, North Carolina, Unite Alcami Corp. is a world-class fully-integrated end-to-end contract dev and manufacturing organization (C headquartered in North Carolina, w

mergr

Product

Mergr for Salesforce
Mergr Data Direct
Mergr M&A Archive
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EXHIBIT C

businesswire
A BERKSHIRE HATHAWAY COMPANY

NovaQuest Private Equity Acquires CoreRx, Inc.

New Strategic Financial Sponsor to Support Continued Growth and Capability Expansion

January 19, 2021 06:30 AM Eastern Standard Time

RALEIGH, N.C. & CLEARWATER, Fla.--(BUSINESS WIRE)--NovaQuest Private Equity (“NovaQuest”) today announced its acquisition of CoreRx, Inc. (“CoreRx” or the “Company”), a global contract development and manufacturing organization (“CDMO”).

Based in Clearwater, FL, CoreRx provides clinical and commercial CDMO services to a wide range of small to mid-sized pharmaceutical and biotech clients. Founded in 2006, the Company offers preformulation, formulation, analytical and stability, clinical manufacturing, commercial manufacturing, and packaging services. The Company’s deep development expertise allows it to solve complex formulation challenges. Its small-batch manufacturing capabilities, coupled with a responsive customer mindset, allow CoreRx to be a nimble, hands-on partner for its valued customers.

“This transaction is an endorsement of CoreRx’s success to date and its potential for future growth with NovaQuest, a firm with deep healthcare and life sciences expertise and a long history of partnering with market-leading businesses to take them to the next level,” said Todd R. Daviau, President and CEO of CoreRx. “NovaQuest’s expertise in pharmaceutical services and enabling technologies will be invaluable as we look to further grow and enhance the value of our business in partnership with our customers.”

“Todd and his management team have done an excellent job building CoreRx from the ground up, growing from a small development organization into a high-quality, end-to-end CDMO with proven commercial capabilities,” said Ashton Poole and Jeff Edwards, Partners at NovaQuest. “We look forward to supporting the CoreRx team as they continue to build out their capabilities and provide best-in-class service to the pharmaceutical industry.”

Affiliates of Signet Healthcare Partners, an investor in CoreRx since 2015, will retain a minority position.

Goldman Sachs Specialty Lending Group provided debt financing for the transaction. Ingram Micro Commerce served as exclusive financial advisor to CoreRx. Sheppard Mullin and Johnson Pope served as legal advisors to CoreRx, and Smith Anderson served as legal advisor to NovaQuest. Deal terms were not announced.

About CoreRx:

CoreRx is a CDMO with full-service capabilities to support clinical through commercial manufacturing, offering state of the art facilities to support your supply chain needs. Our integrated offerings provide comprehensive services for the development, manufacturing, and testing of solid, liquid, and semi-solid dosage forms. For more information, please visit www.corerxpharma.com.

About NovaQuest Private Equity:

NovaQuest Private Equity is a leading investor in technology and services companies in the life sciences and healthcare sectors. NovaQuest was formed in 2000 with the vision of building an investment platform to provide strategic capital and operational leverage in partnership with strong management teams. The investment team consists of highly seasoned operational and investment professionals with significant investment experience and deep life science and healthcare expertise. Furthermore, NovaQuest benefits from an extensive network of industry experts and relationships that assist in identifying, analyzing and growing NovaQuest portfolio companies and investments. For more information, please visit www.novaquest.com.

Contacts

For further information about CoreRx:
Mark DaFonseca, Chief Business Officer
(727) 259-6950, mark.dafonseca@corerxpharma.com

For media inquiries:
Jeremy Milner, BackBay Communications
(401) 862-9422, jeremy.milner@backbaycommunications.com

Exhibit D

NovaQuest Capital Management Acquires CutisPharma, Inc.

NEWS PROVIDED BY
CutisPharma, Inc. →
Mar 26, 2018, 06:00 ET

WILMINGTON, Mass., Mar. 26, 2018 /PRNewswire/ -- CutisPharma, Inc. ("CutisPharma"), a specialty pharmaceutical company that for two decades has been the industry leader in providing innovative solutions to pharmacists, with its recently approved 505(b)(2) NDA for FIRVANQ™ vancomycin oral solution kit by the FDA, today announced that it has been acquired by NovaQuest Capital Management, L.L.C. ("NovaQuest"). As a part of the transaction, Goldman Sachs Specialty Lending Group has provided financing to further support CutisPharma's growth requirements. Financial terms were not disclosed. TAP Advisors acted as financial advisor to CutisPharma.

"We welcome the opportunity to collaborate with Neal and the rest of the CutisPharma management team and look forward to helping the Company continue its impressive growth trajectory," said Jeff Edwards of NovaQuest. "CutisPharma is an excellent fit with NovaQuest's philosophy of providing strategic capital to growing businesses that reduce the cost of care, meet unmet medical needs, improve efficacy, and/or improve quality of life."

Founded in 1998, CutisPharma develops and commercializes unit-of-use kits, under the FIRST® Kit brand, to aid pharmacists in compounding prescriptions conveniently, and in compliance with compounding regulations. CutisPharma's rapidly expanding portfolio of kits is utilized in thousands of retail and hospital pharmacies across the United States. CutisPharma recently announced the approval of its FIRVANQ™ (vancomycin hydrochloride) for oral solution kit,

which upon launch will be the only FDA-approved oral vancomycin solution treatment commercially available, improving patient access and reducing pharmacist burden by no longer having to compound oral liquid formulations.

"The transaction is an endorsement of CutisPharma's success to date and its potential for future growth with NovaQuest, a firm with deep healthcare and life sciences expertise and a long history of partnering with market-leading businesses to take them to the next level," said Neal Muni, MD, MSPH, CEO of CutisPharma. "NovaQuest's expertise in pharmaceutical services and enabling technologies will be invaluable as we look to further grow and enhance the value of our business in partnership with our customers."

About CutisPharma

CutisPharma, Inc., based in Wilmington, Mass., is a specialty pharmaceutical company that has been the industry leader for 20 years in providing innovative solutions to pharmacists. CutisPharma's FIRST® Unit-of-Use Compounding Kits have benefited millions of patients who are unable to swallow conventional oral dosage forms such as tablets and capsules and whose needs are not served by commercially available therapies. The Company's first FDA-approved kit, FIRVANQ™, will improve patient access and aid pharmacists in conveniently delivering safe, affordable and easily verifiable, oral liquid formulations to patients. For more information, visit www.cutispharma.com.

About NovaQuest Capital Management, L.L.C.

NovaQuest Capital Management is a leading investor in life sciences and healthcare through our BioPharma and Private Equity strategies. NovaQuest was formed in 2000 with the vision of building an investment platform to provide strategic capital to life sciences and healthcare companies. Today, NovaQuest Capital Management manages over $1.8 billion through its BioPharma and Private Equity strategies. The investment team consists of highly seasoned operational and investment professionals with significant investment experience and deep life science and healthcare expertise. Furthermore, NovaQuest benefits from an extensive network of industry experts and relationships that assist in identifying, analyzing and growing NovaQuest portfolio companies and investments. For more information, please visit www.novaquest.com.

SOURCE CutisPharma, Inc.

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